UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CARL D. CACHIA, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

BELLUS HEALTH INC., ROBERTO BELLINI, FRANÇOIS DESJARDINS, DR. CATHERINE BONUCCELLI, DR. JACKY SMITH, JEFFERIES LLC, COWEN AND COMPANY, LLC, GUGGENHEIM SECURITIES, LLC, ROBERT W. BAIRD & CO. INCORPORATED, and BLOOM BURTON SECURITIES INC.,

Defendants.

No. 1:21-CV-02278-GBD

ORAL ARGUMENT REQUESTED

(LEAVE TO FILE ADDITIONAL PAGES GRANTED NOV. 5, 2021)

MEMORANDUM OF LAW IN SUPPORT OF BELLUS DEFENDANTS' MOTION TO DISMISS THE AMENDED CLASS ACTION COMPLAINT

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PRELIMINARY STATEMENT

In July 2020, Canada-based publicly-traded pharmaceutical developer BELLUS Health Inc. ("BELLUS" or the "Company") announced disappointing news: BELLUS's first clinical trial for its only drug candidate did not show that the drug worked to a statistically significant level in people with chronic cough. There was, however, a bright spot: the drug did work, to a statistically significant degree, in patients with a particularly high cough frequency. That drug, BLU-5937, is now undergoing further clinical testing with enhanced focus on these high-frequency coughers.

Understandably, BELLUS's stock traded down following the disappointing news. More than eight months later, this strike suit was filed by a purported BELLUS stockholder ("Plaintiff").[1] Bringing claims under both the Securities Exchange Act of 1934 (the "Exchange Act") and Securities Act of 1933 (the "Securities Act")—the latter alleged for the first time in the AC, filed 14 months after BELLUS's alleged July 2020 corrective disclosure—Plaintiff alleges that BELLUS materially misled the market. Yet Plaintiff does not claim that anything BELLUS ever disclosed is untrue. Instead, Plaintiff's claim is essentially that BELLUS somehow ***should*** have known ***ahead of time*** the ultimate outcome of its double-blind clinical trial.

Plaintiff clouds this nonsensical fraud by hindsight allegation in an argument that BELLUS should have known and disclosed that the trial was supposedly poorly designed based on the trial results of other, similar drugs being developed by competitors. But this too is nonsense. As this Court and the Second Circuit have repeatedly held, "securities law is not 'a tool to second guess how clinical trials are designed and managed.'" *Zagami v. Cellceutix Corp.*, 2016 WL 3199531, at *12 (S.D.N.Y. June 8, 2016). Moreover, BELLUS truthfully disclosed not only the specifics of

[1] The Amended Complaint ("AC") brings claims against BELLUS, certain Company executives, including BELLUS President and CEO Roberto Bellini; Senior VP of Finance François Desjardins; and Chief Medical Officer Dr. Catherine Bonuccelli (together, the "Individual Defendants," and with BELLUS, the "BELLUS Defendants"), as well as others. (AC ¶¶ 24-26.) The AC added the underwriters in BELLUS's U.S. offering, but this Court granted the stipulated dismissal of Plaintiff's claims against the underwriters on Nov. 16, 2021. (ECF No. 53.)

its trial design—so that investors could review its merits for themselves—but also warned investors of competition from the very competitors' drugs about which Plaintiff now complains. Plaintiff's Securities Act and Exchange Act claims both fail for that reason alone. However, as set forth in detail below, there are also multiple, independent bases for dismissal here:

- ***No Scienter (Exchange Act Claims):*** The AC fails to allege any particularized facts supporting even a plausible inference of scienter, much less the requisite "strong inference." Plaintiff alleges no motive to commit fraud—*e.g.*, there are no allegations of improper trading—and the AC fails to satisfy its "correspondingly greater" burden of alleging that Defendants knew, or were reckless in not knowing, that any statement was false or misleading when made. Indeed, the AC lacks a single particularized fact—from a confidential witness, document, or otherwise—to provide any basis about Defendants' knowledge. At the very least, the AC's illogical scienter theory is not as strong as the obvious non-fraudulent inference that is supported by BELLUS's public disclosures.
- ***No Materially Misleading Statement (All Claims):*** The AC alleges no affirmative misleading statements, instead proceeding entirely on an omissions theory. Yet Plaintiff does not, and cannot, point to a single presently-existing fact needed to make Defendants' truthful statements (regarding BELLUS's study designs) or forward-looking, optimistic opinions (regarding clinical trial prospects) not misleading. Plaintiff's entire theory amounts to a gripe that BELLUS made the wrong ***strategic*** and ***scientific judgment calls*** in designing the trial at issue. However, as this Court's precedents confirm, such disagreements are not actionable under the securities laws.
- ***No Loss Causation (Exchange Act Claims):*** The AC alleges only that BELLUS's stock price fell following disappointing news—but does not allege, as Plaintiff must, that the subject of Defendants' alleged misstatements was the cause of the loss suffered.
- ***Barred By The Statute of Limitations (Securities Act Claims):*** The Securities Act's one-year statute of limitations began to run in July 2020, when the AC alleges that Defendants "revealed the truth" of their alleged misstatements. Yet Plaintiff did not file the AC until September 2021, months after the limitations period's July 2021 expiration date. And because the AC's theory of an alleged trial "design flaw" is entirely new—it was not raised in Plaintiff's initial complaint—the AC is not salvaged by relation back to the original complaint.
- ***No Statutory Standing (All Claims):*** BELLUS's stock is listed both in Canada (on TSX) and the U.S. (on NASDAQ). The AC wholly fails to allege where, how, or under what circumstances Plaintiff allegedly acquired his BELLUS stock. There is accordingly no factual basis for a securities claim under U.S. law. The AC also fails to allege how Plaintiff's shares are traceable to the at-issue Offering, a necessary precondition to his Securities Act claims.
- ***No Personal Jurisdiction (All Claims):*** Because BELLUS and its employees are based in Canada, and Plaintiff fails to allege a nexus between his stock trades (the basis of his claims) and the United States, the AC should be dismissed for lack of personal jurisdiction.

For all of these reasons, the AC should be dismissed with prejudice.

BACKGROUND[2]

A. BELLUS Health, Refractory Chronic Cough, and Potential Treatments.

Headquartered in Quebec, Canada, BELLUS is a clinical stage biopharmaceutical company focused on addressing the unmet medical needs of patients suffering from chronic cough and other hypersensitization disorders. (Ex. 3, Form SUPPL ("Prospectus") at S-2, S-61.) BELLUS is not large: the Company had twelve employees as of August 2019 and 32 employees as of February 2021. (*Id.* at S-61; Ex. 28 at 23.) BELLUS began trading publicly on the Toronto Stock Exchange ("TSX") in May 2012, and became cross-listed on both TSX and NASDAQ on September 5, 2019, with BELLUS's issuance of the final Prospectus for its initial public offering in the United States (the "Offering"). (Ex. 3 at S-65; AC ¶¶ 102-03.)[3]

The Company's only product candidate, BLU-5937, is currently in Phase 2 clinical trials. (Ex. 3 at S-10; Ex. 4 (Ex. 99.1) at 6.) The primary indication for BLU-5937 is the treatment of chronic cough; *i.e.*, a cough lasting for more than eight weeks, and in some patients for many years. (Ex. 3 at S-2-4.) BLU-5937 is part of a class of drugs that inhibit a sensory nerve receptor called P2X3. Overstimulation of P2X3 is thought to cause chronic cough and other hypersensitivity conditions. (*Id*. at S-37-38.) The basic idea is that by suppressing the receptor, BLU-5937 may calm the nerves, thus suppressing the overactive cough reflex.

BLU-5937 is not the only P2X3 inhibitor in development. In addition to BELLUS,

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[2] The following facts are drawn from the AC, as well as exhibits to the Declaration of Caroline H. Bullerjahn, which are cited to as "Ex. _." These exhibits are documents that courts in this Circuit routinely consider on motions to dismiss securities class actions, including: (i) SEC and other government filings, press releases, and documents that are worthy of judicial notice because they are "matters of public record"; and (ii) documents that are quoted in the AC and thus "incorporated into the AC by reference." *In re Aratana Therapeutics Inc. Sec. Litig.*, 315 F. Supp. 3d 737, 743 n.1 (S.D.N.Y. 2018); *accord, e.g.*, *In re Kandi Tech. Grp., Inc. Sec. Litig.*, 2019 WL 4918649, at *1 n.1 (S.D.N.Y. Oct. 4, 2019) (taking judicial notice of "press releases and earnings call transcripts" in granting motion to dismiss).

[3] The Prospectus Supplement filed with the SEC incorporated BELLUS's base shelf prospectus dated July 26, 2019. (*See* Ex. 3 at 1.) The Prospectus includes the disclosures BELLUS filed on Form F-10 and F-10/A in September 2019 and is synonymous with the "IPO Documents" as described in the AC. (*See* AC ¶¶ 101-02.)

pharmaceutical giants Merck & Co., Bayer AG, and Shionogi Inc. are all developing drugs to compete in this space. (*Id.* at S-15.) Of these drugs, the "most advanced in clinical development" is Merck's, gefapixant. (*Id.* at S-3) Before BELLUS even initiated Phase 1 trials on BLU-5937, gefapixant had already undergone Phase 2 clinical trials, which had shown that gefapixant could reduce patients' cough frequency. (*Id.*) But gefapixant has relatively "low selectivity" of P2X3 and interacts with a similar receptor involved in taste. (*Id.* at S-36.) So, while gefapixant reduced cough, it also caused significant side effects, including complete taste loss in some patients. (*Id.* at S-39-40.) BLU-5937, by contrast, is "specifically designed to be a highly selective inhibitor of the P2X3 receptor," leading the Company to "believe that BLU-5937 . . . has the potential to significantly alleviate refractory chronic cough while maintaining taste function." (*Id.* at S-40.)

B. Clinical Drug Trials And The FDA Approval Process.

The Food and Drug Administration ("FDA") administers the approval process for any drug ultimately sold in the United States. Drugs must show both safety and efficacy for approval. Sponsors, like BELLUS, guide those compounds through a complex regulatory regime, from the early filing of an Investigational New Drug Application ("IND"), based largely on chemical and animal testing, through progressively more extensive human clinical trials. 21 C.F.R. §§ 312.20, 312.21. These trials generally follow three Phases that include increasingly more patients as the drug sponsor gains the necessary proof of safety and effectiveness for approval. *Id.*

At each trial stage, the sponsor must set enrollment criteria for participants, both for study ***inclusion*** (*e.g.*, having the disease or symptoms under investigation) and study ***exclusion*** (*e.g.*, having another diagnosis that could cause the symptoms at issue). As the FDA has described, setting these criteria involves tradeoffs. On the one hand, narrow criteria can create "a homogenous sample of subjects" and reduce confounding factors. But, "[o]n the other hand, narrow eligibility criteria can diminish the understanding of the risk-benefit of the study treatment

relevant to the patient population likely to take the drug if the drug is approved. ***Sponsors must balance*** the need to generate evidence of effectiveness to support a regulatory decision while obtaining evidence in the population most likely to utilize the treatment."[4]

C. Before Issuing The Prospectus, BELLUS Designed The RELIEF Trial Consistent with Competitors' Trials.

BELLUS had success with BLU-5937 in animal trials, reporting that "in a guinea pig cough model, BLU-5937 showed comparable anti-tussive [anti-coughing] efficacy to [gefapixant]." (AC ¶ 73 & n.9; Ex. 5, 7/19/18 Press Release.) Based on these results, in July 2018, BELLUS announced it would pursue a Phase 1 trial in healthy subjects (*i.e.* without chronic cough) to assess the "safety" and "tolerability (including taste perception)" of BLU-5937. (*Id.*) On November 19, 2018, BELLUS announced the positive results of that trial—the 24 participants reported no total loss of taste. (AC ¶ 74 & n.10; Ex. 6, 11/19/18 Press Release.) Phase 2 trials were next.

The FDA accepted BELLUS's IND for BLU-5937 on April 30, 2019. (AC ¶ 75.) BELLUS then designed its initial Phase 2 trial for BLU-5937—a double-blind, placebo-controlled trial called "RELIEF"—and set RELIEF's enrollment criteria on June 6, 2019. (AC ¶ 96 & n.25; Ex. 7, Clinical Trial Record for NCT03979638.)[5] The "key inclusion criteria" were that patients have (1) "unexplained or refractory chronic cough for at least one year," (2) "a cough count of [greater than or equal to] 10 per hour," and (3) "a score of [greater than or equal to] 40mm on the Cough Severity VAS." (Ex. 3 at S-42.) BELLUS enrolled its first RELIEF patients in July 2019 and completed enrollment in March 2020. (AC ¶ 96 & n.25; Ex. 8, 7/30/19 Press Release; AC ¶ 156 & n.54; Ex. 9, 3/19/20 Press Release.) BELLUS issued the Prospectus on September 5, 2019, *i.e.*,

[4] FDA, Public Workshop: Evaluating Inclusion And Exclusion Criteria In Clinical Trials, at 2 (Apr. 16, 2018), https://www.fda.gov/media/134754/download (emphasis added).

[5] "'Double blind' means that 'both subjects and investigators . . . are unaware of each subject's assigned treatment.'" *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 519 n.4 (S.D.N.Y. 2015), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016). Therefore, none of the Company, the trial investigators, or the enrolled patients knew whether patients received BLU-5937 or a placebo during the course of the trial until after its completion.

a few months after initiating RELIEF and in the midst of the patient enrollment process. At that point, RELIEF's design was consistent with the design of clinical trials for three competitor drugs:

- Merck: The AC references two Phase 2b trials of gefapixant. (AC ¶¶ 77, 81.) The first, which reported positive topline results in 2016, had no minimum cough threshold requirement. (AC ¶¶ 77-80 & n.12; Ex. 10, Clinical Trial Record for NCT02349425; Ex. 11, Clinical Trial Record for NCT02612610.) Instead, the primary inclusion criteria were chronic cough for a year or more (as with RELIEF) and a 40 mm cough severity score or more (as with RELIEF). (*Id.*) The second Merck trial, which reported positive topline results in 2017, had even fewer inclusion criteria. (AC ¶¶ 81-83 & n.16; Ex. 10; Ex. 11) It required only that patients have chronic cough, but had no minimum threshold for coughs per hour or cough severity. (*Id.*) In 2018, Merck began two Phase 3 clinical trials for gefapixant. (AC ¶ 87.) Like Merck's Phase 2 trials, neither Phase 3 trial required participants to have a minimum number of coughs per hour. (*Id.*; Ex. 12, Clinical Trial Record for NCT03449134; Ex. 13, Clinical Trial Record for NCT03449147.) Indeed, Merck's Phase 3 trials did not even include a cough severity requirement—participants simply had to have a chronic cough for at least a year. (*Id.*)

- Bayer: On July 25, 2019 (shortly after the RELIEF trial began), Bayer reported that its candidate, BAY1817080 (ellapixant), met its endpoints in a Phase 1/2a trial. (AC ¶¶ 91-92.) The trial had no cough per hour threshold for enrollment. (Ex. 14, Clinical Trial Record for NCT03310645.)

- Shionogi: In March 2019, the company released topline results from a "proof of concept" study of its drug candidate, S-600918 (sivpixant). (AC ¶ 88.) But, like Bayer, Shionogi did not report on study participants' baseline coughs per hour. Based on Japan's equivalent public clinical trials database, the trial had no minimum cough threshold for enrollment. (Ex. 15, Clinical Trial Record for JapicCTI-184027.)

BELLUS designed the RELIEF trial against this backdrop. While ***no*** competitor's trial had required a minimum frequency of coughs per hour (instead using the presence of chronic cough or cough severity as criteria), RELIEF required patients to have ***at least*** 10 coughs per hour, on top of criteria for cough severity and chronic cough length. And while the AC alleges that competitors' studies ended up with patient populations with high cough counts, only one study—Merck's initial Phase 2 trial—allegedly reported an average cough count before BELLUS issued the Prospectus. (AC ¶ 77 n.13; Ex. 16, 5/16/16 Press Release (reporting "a mean awake cough average of almost 60 times per hour").) The other trials either never reported that data (Bayer) or reported it only ***after*** RELIEF was underway and the Prospectus had been issued. (AC ¶ 110

(Shionogi); AC ¶ 82 n.17 (Merck).) Further, no competitors had reported results specifically for a subgroup of patients with a higher cough count; study results were based on the entire participant population, whether low or high count. The chart below summarizes the status of P2X3 clinical trials when BELLUS crafted its RELIEF trial design, and made its Prospectus disclosures:

Company (Product)	Trial Type	Enrollment Min. Cough Severity?	Enrollment Min. Cough/hr?	Reported Results for Higher Cough/hr Cohort?
Merck (Gefapixant)	Phase 2b	Yes, 40 mm	**No**	No
Merck (Gefapixant)	Phase 2b	No	**No**	No
Merck (Gefapixant)	Phase 3	No	**No**	-
Merck (Gefapixant)	Phase 3	No	**No**	-
Bayer (Ellapixant)	Phase 1/2a	Yes, 40 mm	**No**	No
Shionogi (Sivpixant)	"Proof of Concept"	No	**No**	No
BELLUS (BLU-5937)	Phase 2	Yes, 40 mm	Yes, 10 cough/hr	-

D. BELLUS's Prospectus Thoroughly Disclosed BLU-5937 Development Risks.

Before BELLUS shares began trading on NASDAQ, over 44 million common shares were already in circulation on TSX. (Ex. 3 at S-6, S-62-65). On September 5, 2019, upon completing its Prospectus filing with the SEC (*see supra*, note 2), BELLUS (1) dual listed its existing shares on NASDAQ in the United States; and (2) registered 9.9 million additional common shares on NASDAQ, with an additional 1.5 million shares that could optionally be purchased by BELLUS's underwriters. (Ex. 3 at S-6.) This was a "firm-commitment" offering, in which BELLUS's underwriters agreed to purchase all BELLUS shares sold in the Offering. (*Id.* at S-75.) With the NASDAQ listing, certain entities agreed to "lock up" (*i.e.*, not sell) their shares for 90 days, until December 4, 2019. (*Id.* at S-76-77.)

The Prospectus runs over 100 pages, containing extensive disclosures of the Company, BLU-5937's development, and the competitive landscape. For example, the Prospectus informed investors that "[t]he only clinically validated treatments in development for refractory chronic

cough are molecules that inhibit the P2X3 receptor"; that gefapixant was "the most advanced" such inhibitor in development; and that BELLUS "believe[d] that BLU-5937 had best-in-class selectivity for" P2X3 so that it could "potentially eliminat[e] the taste loss" of gefapixant. (*Id.* at S-39.) In the Prospectus, the Company predicted (accurately) that it would read out initial RELIEF trial data in "mid-2020." (*Id*. at S-41.) The Prospectus never guaranteed success, nor that a Phase 3 trial would be the next step for BLU-5937. Instead, it stated:

> We are actively recruiting patients in a Phase 2 clinical trial to evaluate the efficacy, safety, and tolerability of BLU-5937 in refractory chronic cough patients . . . . ***If*** our Phase 2 clinical trial is successful, we expect to initiate ***either a Phase 2b*** or a Phase 2/3 trial to further pursue the development of BLU-5937 for the treatment of chronic cough. (*Id.* at S-4 (emphasis added), S-37, S-44.)

The Prospectus described the RELIEF trial in detail, including its anticipated size (65 patients), dosages, length, endpoints to determine efficacy, and "key inclusion criteria," including, specifically, that participants have at least 10 coughs per hour at baseline. (*Id.* at S-41-42.) The Prospectus included extensive, specific disclosures of the risks facing BLU-5937 (*see id.* at S-10-28), as well as cautionary warnings regarding forward-looking statements, such as BELLUS's predictions and beliefs (*see id.* at S-33-35). Particularly relevant here, the Company warned:

- We currently believe that our growth and future prospects are mainly dependent on the successful development, regulatory approval and commercialization of our product candidate BLU-5937, ***which may never occur***. (*Id.* at S-10 (emphasis added).)

- ***The clinical effectiveness of BLU-5937 is not yet supported by clinical data.*** . . . and the medical community has not yet developed a large body of peer reviewed literature that supports the safety and efficacy of BLU-5937. If future studies call into question the safety or efficacy of BLU-5937 . . . our business, financial condition, results of operations or prospects could be adversely affected. (*Id.* at S-12.)

- ***Our clinical trials may not yield results that will enable us to obtain regulatory approval for our current or future product candidates.*** . . . We do not know whether our current or any future clinical trials will demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals or if they will result in marketable products. (*Id.* at S-12.)

- Based on results at any stage of clinical trials, we may decide ***to repeat or redesign a trial*** or

discontinue the development of a product candidate. . . . If we fail to adequately demonstrate the safety and efficacy of BLU-5937, we will not be able to obtain the required regulatory approvals to commercialize that product candidate. (*Id.* at S-12 (emphasis added).)

- ***We may not achieve our projected development goals in the announced and expected time frames.*** . . . The actual timing of these events can vary dramatically due to factors such as delays or failures in clinical trials . . . . There can be no assurance that our clinical trials will be completed, that we will make regulatory submissions or receive regulatory approvals as planned, or that we will be able to adhere to our current schedule for the launch of BLU-5937 or any other future product candidates we may develop. (*Id.* at S-14.)

The Prospectus also highlighted the risks associated with designing a clinical trial and setting enrollment criteria, including—just as the FDA describes in its guidance (*see supra* at 4-5)—that such criteria can affect enrollment and impact the development process:

- ***If we encounter difficulties enrolling patients in clinical trials, the trials could be delayed or otherwise adversely affected.*** . . . [We] may not be able to enroll a sufficient number of patients to complete clinical trials in a timely manner. Patient enrollment is a function of many factors, including . . . design of the protocol . . . [and] eligibility criteria for the trial in question . . . . If [we] have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay or terminate ongoing clinical trials. (*Id.* at S-12.)

The Prospectus also expressly disclosed the three other players in this market (Merck, Bayer, and Shionogi) and warned that these competitors could outcompete BELLUS:

- ***Competition in the biopharmaceutical industry is intense, and development by other companies could render our product candidate or any future product candidates or technologies noncompetitive*** . . . Merck, Bayer and Shionogi are developing P2X3 antagonists for chronic cough that could compete directly with BLU-5937. (*Id.* at S-15.)

- Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. (*Id.* at S-48.)

E. Post-Prospectus Filing, BELLUS Kept Investors Up-to-Date On Its Progress.

Because RELIEF was double-blind (*i.e.*, neither BELLUS, nor trial sites, nor patients knew whether patients received BLU-5937 or placebo), no one at BELLUS knew or could have known the trial's outcome before completion. Thus, after issuing the Prospectus, the Company reiterated the same basic facts about RELIEF in press releases, SEC filings, and presentations as BELLUS

moved towards its mid-2020 data readout,[6] for instance reiterating that "***if*** our Phase 2 clinical trial is successful, we ***expect*** to initiate either a ***Phase 2b*** or a Phase 2/3 trial." (Ex. 4 (Ex. 99.1) at 5, 13 (emphasis added); AC ¶ 196 & n.65; Ex. 21, 4/13/20 Jefferies Report.) BELLUS also presented at conferences where it described the same key science summarized in the Prospectus: (a) competitors' P2X3 inhibitors had success in clinical trials, showing the effectiveness of P2X3 as a target; (b) preclinical testing (*i.e.*, in animals and test tubes) of BLU-5937 was promising and showed similar results to competitors; and (c) BLU-5937 showed less of a taste effect in humans.[7]

On March 19, 2020, BELLUS announced that it completed enrollment in the RELIEF trial. (AC ¶ 156; Ex. 9.) On April 6, 2020, the Company announced that it completed dosing of RELIEF participants as well. (AC ¶ 158; Ex. 26.) While BELLUS had enrolled 68 patients in the study, several patients dropped out due to the onset of the COVID-19 pandemic, leaving 52 to complete dosing. (*Id.*) With only 52 remaining patients, the Company estimated that "the RELIEF trial is powered at more than 80% to see a 30% difference between BLU-5937 and placebo in awake cough frequency." (*Id.*)[8] Put differently, BELLUS was explaining that the RELIEF trial had a 20% chance of ***failure*** even if BLU-5937 ***worked*** similarly to its competitors.

Also following the issuance of the Prospectus, Merck, Bayer, and Shionogi released additional information concerning their respective drug candidates. According to the AC, on or

[6] (*See* AC ¶ 143 & Ex. 17, Nov. 14, 2019 Press Release (Nov. 19, 2019 6-K, Ex.99.1); ¶ 146 & Ex. 18, Jefferies London Healthcare Conference Presentation (Nov. 20, 2019); ¶ 149 & Ex. 19, Feb. 27, 2020 Press Release (Feb. 27, 2020 6-K Ex. 99.1); ¶ 153 & Ex. 20, Cowen 40th Annual Health Care Conference Presentation (Mar. 3, 2020); ¶ 156 & Ex. 9; ¶ 158 & Ex. 26, April 6, 2020 Press Release (April 6, 2020 6-K, Ex. 99.1.)

[7] (*See* AC ¶ 161 & Ex. 22, Bank of America Securities 2020 Health Care Conference Transcript (May 12, 2020); ¶ 164 & Ex. 23, Annual Shareholder Meeting Shareholder/Analyst Call Transcript (May 14, 2020); ¶ 166 & Ex. 24, BLU-5937 Update & Chronic Cough KOL Meeting Transcript (May 27, 2020); ¶ 170 & Ex. 25; ¶ 172 & Ex. 25, BLU-5937 Update & Chronic Cough KOL Meeting Presentation (May 27, 2020).)

[8] "The power of a study is the probability of finding a statistically significant association of a given magnitude (if it exists) in light of the sample sizes used." Michael D. Green et al., Reference Guide on Epidemiology, *in* Reference Manual on Scientific Evidence, 582-83 (Federal Judicial Center 3d ed. 2011). The "power" is the complement of the failure rate: "Thus, a study with a likelihood of [25%] of failing to detect a true [outcome] has a power of [75%]." *Id.*

after September 28, 2019, Shionogi disclosed that average (mean) coughs per hour in its Phase 2a study were approximately 56. (AC ¶ 110.)[9] On March 17, 2020, Merck announced successful topline results in its two Phase 3 trials. (AC ¶¶ 113-14.) In April 2020, Bayer released positive topline results in a Phase 2 trial of its drug candidate. (AC ¶¶ 117-18.) Meanwhile, BELLUS continued to disclose to investors that it faced substantial risks and uncertainties, not only in the RELIEF trial, but in potential competition from these other drug candidates and companies.[10]

F. BELLUS Disclosed Its RELIEF Trial Results; This Strike Suit Followed.

On July 6, 2020, shortly after the unblinding of the clinical trial data, BELLUS announced RELIEF's topline results. (AC ¶ 199 & n.67; Ex. 27, 7/6/20 Press Release.) While BLU-5937 reduced patients' awake cough frequency, that result was not statistically significant. BELLUS's stock price fell following this disappointing news. (AC ¶ 199.) However, in a pre-specified group of enrolled patients with a cough frequency greater than the trial's median of 32.4 coughs per hour, BLU-5937 did show a statistically significant effect in reducing coughs. (*Id.*; Ex. 27.) Based upon the statistically significant positive RELIEF results in the higher cough population and consistent with its September 2019 Prospectus disclosures, BELLUS is pursuing a larger Phase 2b trial for BLU-5937. (Ex. 28, Form 40-F (Feb. 25, 2021) at 11.) Several months after BELLUS's July 2020 disclosure, Plaintiff filed this action on March 16, 2021 and filed the AC on September 17, 2021.

ARGUMENT

The AC's theory of liability is not premised on a disclosure issue at all. The AC alleges no affirmative misstatements, and alleges no facts that could have been added to the Company's statements. Instead, the AC takes issue with the ***design*** of BELLUS's RELIEF trial. But Plaintiff

[9] The AC notes that Merck's larger Phase 2 trial had an average (mean) baseline c/h of 40.3 and median c/h of 38.9. (AC ¶ 84.) The only source is an article published in 2021, after the end of the Class Period. (AC ¶ 82 & n.17.)
[10] For the Court's convenience, **Exhibit 2** is a chart that summarizes key risk statements throughout the Class Period drawn from documents incorporated by reference into the AC or otherwise judicially noticeable SEC filings.

does not—and cannot—dispute that BELLUS disclosed ***what*** that design was. From its September 2019 Prospectus filing through the present, BELLUS has repeatedly, accurately disclosed RELIEF's protocols, including that the minimum cough threshold was 10 per hour. (*see, e.g.*, Ex. 3 at S-41-42.) Nor did the BELLUS Defendants ever speak with certainty as to RELIEF's outcome—instead, they repeatedly warned that BLU-5937 may "fail to adequately demonstrate the safety and efficacy" it needed. (*Id.* at S-12.) Indeed, the very purpose of conducting a clinical drug ***trial*** is because one does not (and cannot) know the ***results*** ahead of time.

Now knowing those results, and with the benefit of hindsight, Plaintiff evidently believes that the RELIEF trial's cough threshold should have been set higher, and claims that competitors' then-still-ongoing trials showed some higher threshold was required for success. Plaintiff's premise is dead wrong: ***no*** competitor's trial even had ***any*** cough threshold. Even if Plaintiff's premise were correct, however, it would not state a securities claim. BELLUS ***disclosed*** its protocols, and investors thus had at hand all the information necessary to decide whether to invest. While Plaintiff now apparently disagrees with BELLUS's judgment in designing RELIEF, "[p]ut simply, securities law is not 'a tool to second guess how clinical trials are designed and managed.'" *Zagami*, 2016 WL 3199531, at *12.[11] After parsing through all of the AC's noise, that is all Plaintiff has done here. This flaw infects all of the AC's claims, and they should be dismissed for that reason alone. In addition, specific failings abound, which independently warrant dismissal. The Exchange Act claims fail because the AC fails utterly to plead any factual basis for scienter or loss causation. The newly-added Securities Act claims are time-barred. While each statutory claim has its own standards, the AC fails to plead statutory standing under any of them, and further

[11] *Fadem v. Ford Motor Co.*, 2003 WL 22227961, at *4 (S.D.N.Y. 2003) (dismissing 10(b) claim: "It is not the role of the courts to second guess the decisions made in the course of business operations, lest every strategy that goes awry becomes subject to a lawsuit, and corporations are inhibited from following all but the most conservative path.").

fails to plead a basis for personal jurisdiction. The AC should be dismissed with prejudice.

I. THE AC FAILS TO STATE A CLAIM UNDER THE EXCHANGE ACT.

The AC must meet the "heightened" pleading standards of both Rule 9(b) and the Private Securities Litigation Reform Act ("PSLRA") for its claim under § 10(b) of the Exchange Act. *Kleinman v. Elan Corp.*, 706 F.3d 145, 152 (2d Cir. 2013). The PSLRA "expand[s] on the Rule 9(b) standard," requiring that "complaints specify each misleading statement; that they set forth the facts on which [a] belief that a statement is misleading was formed; and that they state with particularity facts giving rise to a ***strong*** inference that the defendant[s] acted with the required state of mind." *Anschutz Corp. v. Merrill Lynch & Co.*, 690 F.3d 98, 108 (2d Cir. 2012) (emphasis added); 15 U.S.C. § 78u-4(b). Courts in this Circuit routinely dismiss securities fraud claims under these exacting standards.[12] Here, the AC's § 10(b) claim fails because it does not, and cannot, plead (i) scienter or (ii) any actionable misstatement or omission.

A. The AC Fails To Plead Facts Giving Rise To A Strong Inference Of Scienter.

For scienter, Plaintiff must "plead with particularity facts giving rise to a ***strong*** inference that the defendant[s] acted with the required state of mind," which is "an intent to deceive, manipulate, or defraud." *ECA, Local 134 IBEW Joint Pension v. JP Morgan Chase*, 553 F.3d 187, 198 (2d Cir. 2009) (emphasis added). A "strong" inference "must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of

[12] *See e.g.*, *Tongue*, 816 F.3d 199 (affirming dismissal for lack of actionable misstatements); *Kleinman*, 706 F.3d 145 (same); *Lehmann v. Ohr Pharm. Inc.*, 2019 WL 4572765 (S.D.N.Y. Sept. 20, 2019) (no actionable misstatements or scienter); *In re Aratana Therapeutics Inc. Sec. Litig.*, 315 F. Supp. 3d 737 (S.D.N.Y. 2018) (same); *In re Neurotrope, Inc. Sec. Litig.*, 315 F. Supp. 3d 721 (S.D.N.Y. 2018) (same); *Gregory v. ProNAi Therapeutics Inc.*, 297 F. Supp. 3d 372 (S.D.N.Y. 2018), *aff'd*, 757 F. App'x 35 (2d Cir. 2018) (no scienter); *Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557 (S.D.N.Y. 2016) (same); *Fialkov v. Alcobra Ltd.*, 2016 WL 1276455 (S.D.N.Y. Mar. 30, 2016) (no actionable misstatements or scienter); *Sanofi*, 87 F. Supp. 3d 510 (same); *In re EDAP TMS S.A. Sec. Litig.*, 2015 WL 5326166 (S.D.N.Y. Sept. 14, 2015) (no actionable misstatements or scienter); *Abely v. Aeterna Zentaris Inc.*, 2013 WL 2399869 (S.D.N.Y. May 29, 2013) (no actionable misstatements or scienter); *Fort Worth Emps.' Ret. Fund v. Biovail Corp.*, 615 F. Supp. 2d 218 (S.D.N.Y. 2009) (no actionable misstatements, scienter, or loss causation); *In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453 (S.D.N.Y. 2008), *aff'd*, 334 F. App'x 404 (2d Cir. 2009) (no scienter).

nonfraudulent intent." *Id.* To do that, Plaintiff must "show either (1) that defendants had the motive and opportunity to commit fraud, or (2) strong circumstantial evidence of conscious misbehavior or recklessness." *Id.* "Recklessness" must be "conscious . . . *i.e.*, a state of mind ***approximating actual intent***"; that is, "conduct that at the least is highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that ***the danger was either known to the defendant or so obvious that the defendant must have been aware of it.***" *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 109 (2d Cir. 2009) (emphases added).

1. The AC Fails To Allege Motive To Commit Fraud.

The AC wholly fails to allege a motive to commit fraud. Plaintiff "does not allege that [the BELLUS] Defendants engaged in any insider trading during the alleged period of fraud, or otherwise stood to reap personal benefits from allegedly misleading the public about [BLU-5937's] prospects." *Biovail*, 615 F. Supp. 2d at 226.[13] To the contrary, the AC alleges that Defendants, without any reason, "spent years and millions of dollars" investing in a clinical trial they allegedly knew from the outset would fail, "fall[ing] further behind" competitors "in the race towards FDA approval." (AC ¶¶ 12, 220.) "Courts regularly refuse to infer scienter when confronted with such illogical allegations." *Gillis*, 197 F. Supp. 3d at 600-01 (granting motion to dismiss "implausible" allegations that defendant invested "substantial time and resources in clinical studies and NDA submissions that it knew were doomed to fail").[14]

[13] The lack of "allegation that [defendants] sold [] stock" in fact "rebuts an inference of scienter." *Gillis*, 197 F. Supp. 3d at 600; *see also Jackson v. Halyard Health, Inc.*, 2018 WL 1621539, at *8 (S.D.N.Y. Mar. 30, 2018) (dismissing claims); *Gregory*, 297 F. Supp. 3d at 414 (same); *Neurotrope*, 315 F. Supp. 3d at 735 (same).

[14] *See, e.g.*, *In re GeoPharma, Inc. Sec. Litig.*, 411 F. Supp. 2d 434, 446 (S.D.N.Y. 2006) (granting motion to dismiss where "the tenuous plausibility of the alleged scheme substantially weakene[d] the overall strength of plaintiffs' scienter allegations"); *In re Merrill Lynch & Co. Inc., Research Reports Sec. Litig.*, 272 F. Supp. 2d 243, 263 (S.D.N.Y. 2003) (allegations "affirmatively refute[d] scienter" because they contradicted assumption that defendants would act in their own economic self-interest); *Davidoff v. Farina*, 2005 WL 2030501, at *11 n.19 (S.D.N.Y. Aug. 22, 2005) (same); *Hampshire Equity Partners II, L.P. v. Teradyne, Inc.*, 2005 WL 736217, at *3 (S.D.N.Y. Mar. 30, 2005) (fundamentally illogical and contradictory scienter allegations fail as a matter of law); *Cozzarelli v. Inspire Pharms., Inc.*, 549 F.3d 618, 627 (4th Cir. 2008) ("It is improbable that [defendant] would stake its existence on a drug and a clinical trial that the company thought was doomed to failure").

2. The AC Fails To Plead Conscious Misbehavior Or Recklessness.

Because Plaintiff "cannot make the motive showing," the "strength of the [AC's] circumstantial allegations must be ***correspondingly greater***." *ECA*, 553 F.3d at 198 (emphasis added); *Kalnit v. Eichler*, 264 F.3d 131, 143 (2d Cir. 2001) (absent motive, plaintiff "must produce a stronger inference of recklessness"). But again, Plaintiff offers nothing. The AC lacks a single allegation from a confidential witness or document to support any inference—much less satisfy Plaintiff's "correspondingly greater" burden to establish the requisite "strong inference"—that the BELLUS Defendants knew, or were reckless in disregarding information, that any statement was false or misleading when made. *ECA*, 553 F.3d at 198; *In re SLM Corp. Sec. Litig.*, 740 F. Supp. 2d 542, 559 (S.D.N.Y. 2010) (claim "that a defendant merely 'ought to have known' is not sufficient"). Moreover, the AC "make[s] no attempt to establish scienter as to each Individual Defendant. By itself, that warrants dismissal," as "the allegations must establish scienter on a defendant-by-defendant basis." *Schaffer v. Horizon Pharma plc*, 2018 WL 481883, at *11 (S.D.N.Y. 2018); *Aceto*, 2019 WL 3606745, at *8.

Here, the AC attempts three apparent theories supposedly supporting scienter. None do.

First, the AC suggests that efficacy data from competitors' chronic cough studies undermine Defendants' statements about RELIEF, claiming that "the 1934 Act Defendants" (collectively) or "the Company" should somehow have known that RELIEF failed to "adequately account for the correlation between higher cough frequency and higher efficacy" demonstrated by these other studies.[15] The AC lacks any factual support showing that this conclusion was true or known to Defendants. The AC merely points to two Merck trials and one Shionogi trial with mean coughs per hour in the 40s and 50s (AC ¶¶ 4, 110)[16]—but does not allege that Merck or Shionogi

[15] *See* AC ¶¶ 55, 99, 130, 135, 140, 142, 145, 148, 152, 155, 157, 160, 163, 165, 169, 171, 174, 195.
[16] At the time of the Prospectus, only the first Merck trial had released this information, meaning the RELIEF trial

ever released data showing that their drugs' efficacy would have changed based on higher or lower cough frequency.[17] Undercutting the allegations still further, Merck, Shionogi, and Bayer did not include ***any*** minimum number of coughs per hour as a trial enrollment criterion, at the very least suggesting such a requirement was unnecessary.[18] Ultimately, the AC lacks a single allegation—*e.g.*, from "specifically identif[ied] [] reports or statements," *Dynex*, 531 F.3d at 196—showing how any Defendant had any reason to know of a "high risk" that RELIEF would not meet its endpoint or otherwise disbelieve anything they said. *Schaffer*, 2018 WL 481883, at *11 (no scienter where plaintiffs failed to "identify ***with specificity*** the documents or way in which this contrary information ***was communicated to Defendants***" (emphasis added)); *SLM*, 740 F. Supp. 2d at 559.[19]

Second, the AC cites two 2019 analyst reports referencing "recent interactions" with unnamed "cough experts" who allegedly believed an ***acute*** (not chronic) cough study's failure "***could be*** due to trial design" and "***might be*** due to patients not coughing enough at baseline." (*Id.* ¶¶ 127, 129 (emphasis added).) Yet the AC fails to allege that any Defendant, at the time of their challenged statements, even "saw . . . or knew of [the] contents" of these reports, or the vague, unattributed, and speculative statements they allegedly contained. *Pa. Pub. Sch. Emps.' Ret. Sys. v. Bank of Am. Corp.*, 874 F. Supp. 2d 341, 359 (S.D.N.Y. 2012). Nor does the AC contain a basis to believe that the outcome of an acute cough trial was related to the RELIEF chronic cough trial.

Third, in the "Additional Scienter Allegations" portion of the AC (¶¶ 175-84), Plaintiff

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could not have been designed with "correlate[ed]" information beyond a single data point. *See supra* at 6-7; *Youngers v. Virtus Inv. Partners Inc.*, 195 F. Supp. 3d 499, 519 (S.D.N.Y. 2016) (no claim where information was "not available to [Defendants] at the same time they made their misleading statements").

[17] Meanwhile, the AC itself alleges that RELIEF patients had a ***median*** cough frequency of 32.4 coughs per hour—***higher*** than the ***median*** cough frequency (28.9) of patients in Merck's second Phase 2b trial. (AC ¶¶ 4, 84, 199.)

[18] Exs. 10-13 (Merck Trial Protocols); Ex. 14 (Bayer Trial Protocol); Ex. 15 (Shionogi Trial Protocol); *supra* at 6-7.

[19] *Aratana*, 315 F. Supp. 3d at 765 ("[T]he AC does not cite ***any internal documents or confidential witness statements***" (emphasis added)); *City of Brockton Ret. Sys.*, 540 F. Supp. 2d at 473 (no scienter where no informant "offer[ed] any information from which one could infer that [defendants] knew or had reason to know anything").

alleges vaguely that the BELLUS Defendants had access to "material non-public information," but does not even allege what that information was. This plainly fails to meet the PSLRA's requirement to plead scienter with "specificity." *Schaffer*, 2018 WL 481883, at *11; *In re Gentiva Sec. Litig.*, 932 F. Supp. 2d 352, 379-80 (E.D.N.Y. 2013) (granting motion to dismiss: "Plaintiffs should, but do not, provide ***specific instances*** in which Defendants received information that was contrary to their public disclosures" (emphasis added)); *Schaffer*, 2018 WL 481883, at *11.[20]

Finally, "[b]ecause the [AC] fails to allege scienter as to the Individual Defendants, it also fails to allege scienter as to [BELLUS]." *Neurotrope*, 315 F. Supp. 3d at 736.

3. The Non-Fraudulent Inference Outweighs Any Inference of Scienter.

Lacking any insider stock sales, confidential witness allegations, documents, or any other particularized facts concerning Defendants' knowledge, the AC's collective scienter allegations fail to raise ***any*** inference of scienter, much less an inference "more compelling" than competing non-fraudulent inferences the Court must balance. *Loc. No. 38 IBEW Pension Fund v. Am. Exp. Co.*, 724 F. Supp. 2d 447, 463 (S.D.N.Y. 2010) (citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007)).

Here, the opposing inference of nonfraudulent intent is that BELLUS undertook a Phase 2 study, similar in design to competitors' chronic cough studies,[21] to "assess the safety, tolerability and efficacy of BLU-5937 in chronic cough patients"—as the Company repeatedly disclosed[22]—

[20] The AC also lacks any particularized allegation to support the claim that somehow Defendants were "actually aware" prior to the end of the RELIEF trial that "BLU-5937 was not significantly improving patients' coughs." (AC ¶ 179.) The RELIEF trial was ***double-blind***, so ***no one*** knew what the results were prior to unblinding. (AC ¶ 144.)

[21] Like competitors' studies, the RELIEF trial was a "randomized, double-blind, placebo-controlled, dose escalation and two-period crossover design trial to assess the efficacy, safety and tolerability of BLU-5937" at multiple doses. (AC ¶ 143.) *See supra* at 5-7, 9.

[22] *See, e.g.*, *See, e.g.*, Ex. 5, 7/9/18 Press Release; Ex. 6, 11/19/18 Press Release; *see also* Ex. 8, 7/30/19 Press Release ("The RELIEF study is a dose-escalation, placebo-controlled, and crossover design to assess the efficacy, safety, and tolerability of BLU-5937, a highly selective P2X3 antagonist, at four doses; 25, 50, 100 and 200 mg, administered orally, twice-daily"); Ex. 29, 5/14/20 Form 6-K Ex. 99.2 (same); Ex. 3 at S-41; Ex. 7 (RELIEF Trial Protocol).

and that BELLUS Defendants believed in RELIEF's design and enrollment criteria. *See In re Axonyx Sec. Litig.*, 2009 WL 812244, at *4 (S.D.N.Y. Mar. 27, 2009) (granting motion to dismiss: "Any inference of scienter . . . is, to say the least, significantly less compelling than the opposing inference—that [the Company] did its best to design and carry out a successful clinical trial, but that despite these best efforts, [the compound] was not an effective drug . . . .").[23]

The innocent inference here is particularly strong because it finds ample support in (i) BELLUS's transparent public disclosures regarding RELIEF's design and enrollment criteria[24]; and (ii) the Company's repeated cautionary warnings about the risks associated with BLU-5937's potential efficacy and RELIEF's potential outcome.[25] *See supra* at 8-9. These disclosures undercut Plaintiff's scienter allegations: it is "implausible" that Defendants "would perpetrate a fraud predicated on concealing publicly available [information]." *Pa. Pub. Sch. Emps.'*, 874 F. Supp. 2d at 362; *see Gregory*, 297 F. Supp. 3d at 411 (no scienter where defendant "disclosed . . . many of the [trial] design features of which plaintiffs complain"); *City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG*, 752 F.3d 173, 186 & n.62 (2d Cir. 2014) ("disclosure" of risks "undercut the inference" of scienter). There is zero inference of fraud here, let alone an inference that is "cogent and compelling."

B. The AC Fails To Plead Any Actionable Statements.

The Exchange Act claims should also be dismissed for the independent reason that the AC's alleged misstatements and omissions are not actionable. Plaintiff fails to adequately plead that any statement was materially misleading. Many statements are also not actionable as:

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[23] *Gillis*, 197 F. Supp. 3d at 595 ("The substantial time, money, and effort that QRX continued to invest in Study 022 . . . are hard to square with the premise that defendants believed the data from that study was incapable of meeting the FDA's demands. . . the more plausible inference is that defendants sincerely believed [] the Study 022 data was valid").
[24] *See, e.g.*, Ex. 3 at S-42 ("The key inclusion criteria in the RELIEF trial are that patients must have . . . ***a cough count of >= 10 per hour*** (Awake Cough Count at Screening)" (emphasis added)).
[25] *See, e.g.*, Ex. 3 at S-10, S-12-14, S-33-35; *see also* **Exhibit 2**.

(i) immunized forward-looking statements; (ii) immaterial puffery; and/or (iii) protected statements of opinion. *See* Ex. 1 (chart of alleged misstatements and grounds for dismissal).[26]

1. The AC Fails To Plead Any Materially Misleading Statements Or Omissions.

There are "no actionable affirmative false statements in this case," *Kleinman*, 706 F.3d at 156, as Plaintiff does not contend that ***any*** challenged statement is untrue. Instead, in substantially identical text copied nearly verbatim 13 times, the AC claims that Defendants' factual recounting of the various trials was misleading for "fail[ure] to disclose" that BELLUS "disregarded, in designing its Phase 2 trial, the correlation between high cough frequency and high efficacy that Merk's studies had demonstrated," and that RELIEF's alleged "low cough frequency threshold of 10 coughs per hour" was thus a "design flaw" which created "a high risk it would not meet its designated primary endpoint."[27] On this basis, the AC claims that over 50 statements across 12 sources are misleading (AC ¶¶ 138-74). The challenged omissions fall into two categories:

- ***First***, the AC challenges factually accurate statements about BLU-5937's competitor drugs and the RELIEF trial in press releases and SEC filings. All of the quotations drawn from the Prospectus fall into this category, including statements that gefapixant "cause[s] taste alteration and/or taste loss"; that the Phase 2 trials of gefapixant showed "[t]he only clinically validated treatments in development for refractory chronic cough are molecules that inhibit the P2X3 receptor"; that these competitor drugs "could compete directly with BLUE-5937"; and that BELLUS enrolled its first patients in the RELIEF trial in July 2019. (AC ¶¶ 138-39, 141-42.) This category also includes BELLUS's disclosures of the RELIEF trial's design (*e.g.*, "[t]he RELIEF trial is a randomized, double-blind, placebo-controlled, dose escalation and two-period crossover design trial"). (*Id*. ¶ 143-45.)[28]

- ***Second***, the AC challenges statements made by Defendants in lengthy scientific discussions of BLU-5937, the various competitor drugs, and their development to date.[29] These discussions are loaded with (a) factually accurate statements of trial data (*e.g.*, "all of the P2X3 antagonists studied to date, irrespective of selectivity, have resulted in clinically meaningful reductions in

[26] For the Court's convenience, **Exhibit 1** is a chart that quotes the AC's purported materially misleading statements, with context from judicially-noticeable transcripts and SEC filings that are exhibits to the Bullerjahn Declaration, and that cross-references legal arguments herein as to why each alleged misstatement and omission is not actionable.
[27] AC ¶¶ 140, 142, 145, 148, 152, 155, 157, 160, 163, 165, 169, 171, 174.
[28] *See also* AC ¶¶ 146-48; ¶¶ 149-52; ¶¶ 153-55; ¶¶ 156-57; ¶¶ 158-60.
[29] AC ¶¶ 161-63; ¶¶ 164-65; ¶¶ 166-69; ¶¶ 170-71; ¶¶ 172-74.

> cough counts versus placebo, with placebo-adjusted reductions between roughly 25% and 35%"); and (b) clearly demarcated statements of opinion and expected future results drawn from that data (*e.g.*, "While comparisons across trial should be make with caution . . ."; "Assuming that these projections are reasonable . . ."). (AC ¶ 170.)

These statements are all non-actionable because the AC fails to "demonstrate with specificity" why any of them was materially misleading, as required by the PSLRA and Rule 9(b). *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 571 (S.D.N.Y. 2014), *aff'd*, 604 F. App'x 62 (2d Cir. 2015); *Kleinman*, 706 F.3d at 153 (affirming dismissal where the "complaint does not allege that anything in [challenged statements regarding clinical trial results] was literally false"). Plaintiff's backwards "design flaw" theory, made entirely in hindsight, fails for a host of reasons:

First, the premise of the AC's omission-based theory is simply not accurate. No other trial mentioned in the AC even ***had*** a minimum cough frequency requirement, *see supra* at 6-7. All that any other trial could have "taught" is that a cough threshold was ***unnecessary*** for success or to enroll patients with sufficiently high coughs per hour. The AC points to a gefapixant study, for example, with a 40.3 cough per hour average as evidence of supposed "enormous undisclosed risks of failure." (AC ¶ 8.) But that study included patients who coughed only ***0.4 times per hour*** and still reported success. (AC ¶ 82 & n.17; Ex. 30 at 124.) Moreover, the AC does not plead that any study revealed better results in patients with higher cough frequency. Indeed, no study mentioned in the AC even broke out the data in that way during the Class Period. *See supra* at 6-7.

Second, BELLUS explicitly ***disclosed***, in its public RELIEF trial protocol,[30] in the Prospectus, and elsewhere, the very "design flaw" on which the AC is premised: *i.e.*, a cough frequency threshold of 10 coughs per hour. BELLUS's "public reporting" thus "precludes the . . . claim of a nondisclosure rendering other statements actionably misleading." *Gregory*, 297

[30] *See* Ex. 7 (listing inclusion criteria for the RELIEF trial, including "***cough count of ≥ 10 per hour*** (Awake Cough Count) at Screening"); *see also, e.g.*, AC ¶ 166 (statement by Defendant Jacky Smith at May 27, 2020 Key Opinion Leader meeting that "[w]e're also selecting patients with ***more than 10 coughs per hour***. . .").

F. Supp. 3d at 411. Against this disclosure backdrop, Defendants had no duty to disclose anything further, as "none of what was omitted was necessary to make [any statement] not misleading." *Kleinman*, 706 F.3d at 153.[31] What is more, and as the AC itself alleges (¶¶ 84, 109-123), BELLUS's competitors publicly disclosed ***their*** clinical trial designs—which had ***no*** cough frequency threshold—and their respective trial results.[32] Thus, any information as to competitors' trial designs and data available to Defendants was equally available to investors, and would not have "been viewed . . . as having altered the 'total mix' of information." *In re Yukos Oil Co. Sec. Litig.*, 2006 WL 3026024, at *21 (S.D.N.Y. 2006) (collecting cases finding no omission where "the undisclosed fact is already in the public domain"). And even if the AC had raised "some fact cutting the other way" about RELIEF, that would do nothing to make either BELLUS's factually accurate statements or optimistic projections of potential success misleading. *Tongue*, 816 F.3d at 212 (quoting *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 189 (2015)). In *Tongue*, the Second Circuit held that even undisclosed concerns about trial design expressed by the ***FDA directly*** to the drug sponsor did not render the sponsor's statements misleading. *Id.* at 211-12; *see In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187, 213 (S.D.N.Y. 2008) (rejecting claim that isolated "red flags" concerning drug rendered statements false). If direct, undisclosed FDA criticism of a trial design is not a materially misleading omission, a potential inference of criticism drawn from publicly-available facts surely is not.[33]

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[31] *See Biovail*, 615 F. Supp. 2d at 231 ("Plaintiff's related 'omission' theory—namely, that these statements are nevertheless actionable, because Defendants did not disclose that the BVF–033 NDA was at greater risk of non-approval (or delayed approval) in light of the FDA's stated preference for single-dose studies in ANDAs for generic versions of Wellbutrin—is equally unavailing. The fact that Biovail used a multiple-dose study in a full-blown New Drug Application for BVF–033—a non-generic, different drug—was simply not material information that Biovail had to disclose in light of the total mix of information available to investors, including the disclosed risk of 'the difficulty of predicting U.S. Food and Drug Administration ... approvals.'").

[32] Exs. 10-16, *see* AC ¶ 116 ("the market used Merck's clinical studies as a barometer for BELLUS").

[33] Moreover, BELLUS specifically told investors that the RELIEF trial could fail, and estimated that risk to be at least 20% even if the drug ***worked***. (*See supra* at 10 & n.8.) The AC discusses at least six other competitors' trials which met success (four for Merck, one each for Shionogi and Bayer). With seven clinical trials at hand, it should be no

Third, Plaintiff's entire theory is not a disclosure claim at all, but rather a backdoor attempt to challenge a scientific and business decision about a trial protocol. Plaintiff seeks to hold the BELLUS Defendants liable for their ***judgment*** in designing the RELIEF trial the way they did. But, as courts have repeatedly held, stockholders cannot use the securities laws to challenge a pharmaceutical company's choice of how to design its own trials. In *Kleinman*, for example, the Second Circuit concluded the plaintiff "simply ha[d] a problem with using *post-hoc* analysis as a methodology in pharmaceutical studies." 706 F.3d at 154. As the Court explained, however, "[its] job is not to evaluate the use of [a scientific] analysis generally," and because the statement at issue "accurately disclosed" the relevant data, it was not misleading. *Id.* at 154-55.[34] So too here. The AC's allegations "amount to a non-actionable critique of defendants' study design," nothing more. *Abely*, 2013 WL 2399869, at *8 (granting motion to dismiss where "plaintiff's critiques . . . all go toward the design of the study," and allegations "amount[ed] to a competing view of how the trial should have been designed, not [a] material misstatement or omission"). This is the exact type of "second guess[ing]" of scientific judgment this Court has repeatedly rejected. *Zagami*, 2016 WL 3199531, at *12 (rejecting 10(b) claim premised on argument that clinical trials focused on wrong endpoint).[35] Plaintiff's theory fails.[36]

Finally, separate from this theory, the AC claims in two paragraphs that Mr. Bellini, "by

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unanticipated surprise that the one-in-five chance of failure landed on BELLUS's trial.

[34] *See In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 878 (9th Cir. 2012) (dismissing securities claim based on "essentially . . . disagreements with the statistical methodology" and rejecting argument that plaintiff was not "challenging . . . the study design").

[35] *In re Keryx Biopharmaceuticals, Inc., Sec. Litig.*, 2014 WL 585658, at *1 (S.D.N.Y. Feb. 14, 2014) ("It would indeed be unjust—and could lead to unfortunate consequences beyond a single lawsuit—if the securities laws become a tool to second guess how clinical trials are designed and managed."); *Abely*, 2013 WL 2399869, at *6 ("The Second Circuit and other tribunals have concluded that the securities laws do not recognize a fraud claim premised on criticisms of a drug trial's methodology, so long as the methodology was not misleadingly described to investors.").

[36] For similar reasons, Plaintiff cannot fault Defendants for not "implement[ing] revised or new trial protocols" once RELIEF was underway. (AC ¶ 128.) Changing the trial design mid-stream would increase costs and risk delay in obtaining results: all part of the "second guess[ing] the decisions made in the course of business operations" that this Court's precedents seek to avoid. *Fadem*, 2003 WL 22227961, at *4.

touting the efficacy shown in the P2X3 Phase 2 trials by Merck, Shionogi and Bayer alongside BELLUS's [trial]" in two presentations, "implied that the Company would have similarly 'positive top line data.'" (AC ¶ 163, 165.) As the word "implied" indicates, Mr. Bellini did not actually say that. Indeed, the AC blatantly misrepresents both presentations, the slides for which expressly ***disclaimed*** a direct comparison, stating "[n]o head to head clinical trials have been conducted; data derived from different clinical trials in different patient populations and with different dosing regimes and protocols."[37] Moreover, on both occasions, Mr. Bellini referred listeners to BELLUS's risk factors, including that the "clinical effectiveness of BLU-5937 is not yet supported by clinical data." And what Mr. Bellini actually said was: "So we do ***feel*** very ***comfortable*** around the power of the trial, considering it's the largest that's been completed with this design." (Ex. 22, Ex. 23 (similar).) Thus, in addition to expressly disclaiming the inference the AC suggests, Mr. Bellini's statements were also non-actionable opinion, *see infra* at 25.[38]

2. The AC's Forward-Looking Statements Are Non-Actionable.

Certain of the AC's alleged misstatements are also "classically" forward-looking statements[39] that are immunized on two independent grounds under the PSLRA's statutory safe harbor,[40] including statements such as "[t]he [RELIEF] trial is evaluating the efficacy and safety of BLU-5937 and is ***expected*** to build on the Phase 1 evidence showing little to no impact on

[37] (*See* Ex. 31, Bank of America Securities 2020 Health Care Conference Presentation (5/12/20); Ex. 32 (Annual Shareholder Meeting Shareholder/Analyst Call Presentation (5/14/20).)

[38] Many statements in the AC outside of the specific allegations of purported misleading statements (AC ¶¶ 136-174) are conclusory hyperbole and do not remotely resemble well-pled allegations. For example, the AC states that "[a]ccording to BELLUS, its executives and advisors, BLU-5937's efficacy was virtually a foregone conclusion based on its high selectivity." (AC ¶ 5; AC ¶ 104.) Yet the AC does not connect this "foregone conclusion" to a single statement of Defendants. The same is true of the AC's allegations concerning BELLUS's alleged "difficulties enrolling the target population"—the allegation is neither connected to any allegedly misleading statement, or to a purported corrective disclosure by Defendants. (AC ¶ 9; AC ¶ 55 (similar); AC ¶ 135 (similar).)

[39] *See* AC ¶¶ 143-45, 149-52, 158-60, 161-63, 164-65, 166-69, 170-71, 172-74. *See also* **Exhibit 1**.

[40] Under the safe harbor, "[a] forward-looking statement is not actionable if it is identified and accompanied by meaningful cautionary language ***or*** . . . the plaintiff fails to prove that it was made with actual knowledge it was false or misleading." *Aratana*, 315 F. Supp. 3d at 755 (granting motion to dismiss); *see* 15 U.S.C. § 78u-5(c).

taste," and "[t]he Company ***expects*** to complete patient enrollment by the end of March, with topline results anticipated in mid-2020," (AC ¶¶ 143, 150 (emphasis added)). ***First***, the statements were accompanied by meaningful, cautionary disclosures, *e.g.*, "risk factors that may affect . . . future results include . . . achievement of forecasted preclinical and clinical study milestones and that actual results may vary once the final and quality-controlled verification of data and analyses has been completed." (Ex. 17; AC ¶¶ 143-44.)[41] ***Second***, the AC does not allege that any Defendant acted with actual knowledge that these statements were false or misleading. *Sanofi*, 87 F. Supp. 3d at 535 (safe harbor applied despite conclusory allegations "that defendants were aware of the FDA's concerns and therefore 'knew or were severely reckless in disregarding' the misleading nature of their statements"); *Gillis*, 197 F. Supp. 3d at 584 (same); *see supra* at 19-23.

3. The AC's Puffery Statements Are Non-Actionable.

Certain of the AC's alleged misstatements[42] are also classic puffery that courts find non-actionable because they are "too general to cause a reasonable investor to rely upon them." *Virtus*, 195 F. Supp. 3d at 538 (labeling company's strategy as "analytic" and "quantitative" was puffery). For example, no "reasonable investor" would rely on "general" statements that BELLUS's "initiation of our Phase 2 RELIEF trial" was a "critical achievement[]" that "positioned BELLUS Health to execute on this year's upcoming milestones and development plans" (AC ¶ 149), or that "[c]ompleting patient enrollment for the RELIEF trial" was an "important achievement" (AC ¶ 156). These statements about "critical" and "important" achievements offer no "concrete information" and thus "amount[] to puffery." *In re SunEdison, Inc. Sec. Litig.*, 300 F. Supp. 3d

[41] ***Every*** allegedly misleading statement referenced in the AC was accompanied by similar cautions about forward-looking statements, such as that they "inherently involv[ed] numerous important risks, uncertainties, and assumptions, known and unknown, many of which are beyond BELLUS Health's control," including risks regarding "the timing and results for the BLU-5937 Phase 2 RELIEF trial." *See, e.g.*, Ex. 3. A complete listing is included in **Exhibit 2**.
[42] *See* AC ¶¶ 149-52, 156-57, 164-65, 170-71. *See also* **Exhibit 1**.

444, 489 (S.D.N.Y. 2018) (statement regarding "organic development opportunities" was puffery).

4. The AC's Statements Of Opinion Or Belief Are Non-Actionable.

Several of the AC's alleged misstatements are also non-actionable statements of opinion,[43] including those preceded by phrases such as "I believe" or "I think," as well as statements concerning the BELLUS Defendants' interpretation of accurately disclosed clinical trial results and methodologies. "Courts have repeatedly held publicly stated interpretations of the results of various clinical studies to be opinions because reasonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions." *Sanofi*, 87 F. Supp. 3d at 543. For example, "[t]he Company ***believes*** that its highly selective P2X3 antagonist can also reduce coughing in patients with chronic cough" (AC ¶ 151), and "I ***think*** everyone really appreciates [data from Merck's Phase 2b study] for the efficacy" (AC ¶ 161), are expressly denoted as statements of opinion. Because the AC fails to allege that the BELLUS Defendants did not honestly believe these statements when made, or reflect unreasonable interpretations of the underlying data, they are not actionable. *See Tongue*, 816 F.3d at 211-14.[44]

C. The AC Fails to Plead Loss Causation.

The Exchange Act claims should also be dismissed for failure to plead loss causation. "[L]oss causation is not adequately pled simply by allegations of a drop in price following an announcement of bad news if the news did not disclose the fraud," *Gentiva*, 932 F. Supp. 2d at 384, and courts dismiss conclusory allegations premised on "the all-but-inevitable decline in the price of [a company's] stock" after the announcement of a drug candidate's poor performance. *Biovail*, 615 F. Supp. 2d at 229 (dismissing 10(b) claim). To plead loss causation, a plaintiff must

[43] *See* AC ¶¶ 149-52, 156-57, 161-63, 164-65, 166-69, 170-71, 172-74. *See also* **Exhibit 1**.
[44] *See also Aratana*, 315 F. Supp. 3d at 754, 758 ("It is not sufficient . . . to allege that an opinion was unreasonable, irrational, excessively optimistic or not borne out by subsequent events.").

allege "that the ***subject*** of the fraudulent statement or omission was the cause of the actual loss suffered.'" *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 173 (2d Cir. 2005).

Both of the challenged stock drops fail to meet this standard. The AC alleges that the initial drop ended "on April 9, 2020, after two days of heavy trading." (AC ¶ 197.) Yet the AC also alleges that BELLUS's "partial disclosure" that "if no minimum efficacy dose is observed, a small Phase 2b may be necessary," came via an "analyst report issued on April 13, 2020," ***after*** the stock price declined. (AC ¶ 196.) BELLUS's alleged "partial disclosure," thus, could not have caused the stock drop. Further, the potential need for a Phase 2b trial—the purported basis of the drop—was no surprise. As early as the September 2019 Prospectus, BELLUS had been telling investors that a Phase 2b trial could be the next step. (Ex. 3 at S-4, S-29, S-37, S-44.) Thus, Plaintiff does not, and cannot, plead any loss "caused by the materialization of the risk concealed by the fraudulent statement" because no such risk had been concealed. *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 107 (2d Cir. 2007).

The second alleged corrective disclosure—BELLUS's July 6, 2020 press release announcing mixed topline results for RELIEF (AC ¶¶ 199-205)—does not meet the loss causation standard either. As in *Biovail*, the AC fails to "identify any 'corrective disclosure' that revealed the existence of some prior alleged misrepresentation" in BELLUS's July 6 press release. 615 F. Supp. 2d. at 229. The AC pleads only a non-actionable, "all-but-inevitable," stock drop following ***news*** of RELIEF's results, not the reversal of "some prior untruth." *Id.* Indeed, while the AC cites six post-disclosure analyst reports, none suggested that BELLUS hid anything about RELIEF's design. Instead, they pointed to previously unknown information (*e.g.*, the trial's cough counts) as the basis for new guidance. (AC ¶¶ 200-05.) The AC, thus, does not allege "that the ***subject*** of the fraudulent statement or omission"—*i.e.*, prior statements about how RELIEF was designed and

compared to competitors' trials—"was the cause of the loss suffered." *Lentell*, 396 F.3d at 173.

II. THE AC FAILS TO STATE A CLAIM UNDER THE SECURITIES ACT.

In addition to the Exchange Act claims, Plaintiff added new claims under the Securities Act in the AC, premised entirely on alleged misleading statements in the Prospectus. Plaintiff's identical theory fails for the same reasons already discussed: there is no actionable statement in the Prospectus. In addition, Plaintiff asserts his "design flaw" theory for the first time in the AC, months after expiration of the Securities Act's statute of limitations, rendering these claims time-barred.

A. The AC Fails To Plead Any Actionable Misstatements Or Omissions.

To start, the Securities Act claims should be subject to Rule 9(b)'s heightened pleading standards because they "are premised on allegations of fraud." *Rombach v. Chang*, 355 F.3d 164, 170 (2d Cir. 2004). Over 250 paragraphs of the AC are premised on nothing ***but*** securities fraud, and every Prospectus statement alleged to be misleading under the Securities Act is included in the AC's Exchange Act claims (even bolded identically). (*Compare* AC ¶¶ 216-17, *with id.* ¶¶ 138-39, 141.) "Because the sole allegations supporting the falsity element of the Section 11 and Section 12(a)(2) claims are all inextricably intertwined with the allegations underlying [the] fraud claims against [Defendants] these claims undisputedly sound in fraud." *In re Axis Cap. Holdings Ltd. Sec. Litig.*, 456 F. Supp. 2d 576, 598 (S.D.N.Y. 2006). The AC's attempt to disclaim fraud and scienter in a single, conclusory paragraph (¶ 206), cannot avoid *Rombach*'s clear doctrine.[45]

[45] *Axis Cap.*, 456 F. Supp. 2d at 598 ("Although Plaintiffs affirmatively state . . . that their Securities Act claims do not sound in fraud, despite that disclaimer—conclusory, self-proclaimed and self-serving though it necessarily is—on a more objective reading it is clear that the claims are premised on factual allegations permeated with accusations of fraudulent conduct . . . . Plaintiffs cannot so facilely put the fraud genie back in the bottle." (citation omitted)). Further, while this entire action is time-barred (*see infra* at 30-32), because Plaintiff did not bring a Securities Act claim until the AC, Plaintiff can only bring such a claim to the extent it "relates back" to the original complaint. *See* Fed. R. Civ. P. 15. The original complaint was grounded entirely in securities ***fraud*** under the Exchange Act, (*see* Compl. (ECF No. 1)), and therefore there are no pleaded facts of innocent or negligent misrepresentation to which the Securities Act claims can relate back. Plaintiff cannot introduce a new theory of innocent misrepresentation now.

Ultimately, though, Plaintiff's claims fail even under Rule 8. The AC's allegations fail to state a Securities Act claim concerning the Prospectus for the same reasons those allegations fail under the Exchange Act: there is no actionable statement or omission. *See supra* at 18-25. Because the challenged disclosures are the same for both sets of claims, the same standards apply under either statute. *See Rombach*, 355 F.3d at 175 ("We analyze the allegations regarding the registration statement in light of the Section 10(b) claims as well, because the Section 10(b) count incorporates as though fully set forth therein the allegations contained in the Section 11 count."). And because Plaintiff "fail[s] to allege any misstatements or omissions . . . that could be found to be material" for the AC's Section 10(b) claim, Plaintiff's "claims under . . . the Securities Act must also fail." *ECA*, 553 F.3d at 206 (affirming dismissal of Securities Act claims).

The AC's failure to allege any "facts that, if true, would demonstrate that the [Prospectus] contained a material misstatement or omission at the time it became effective" is particularly glaring given the Prospectus's timing. *Scott v. Gen. Motors Co.*, 46 F. Supp. 3d 387, 394 (S.D.N.Y. 2014), *aff'd*, 605 F. App'x 52 (2d Cir. 2015) (dismissing Section 11 claim). As of September 2019, when the Prospectus was issued, only one Merck trial had released preliminary data about mean baseline coughs per hour, and that trial did not have (or apparently need) a minimum cough threshold to achieve its results. *See supra* at 6. Neither Shionogi or Bayer had released such data, nor had Merck released baseline cough data from its larger Phase 2 trial. *See supra* at 6-7. In other words, the allegedly omitted facts about other companies' trial designs and results did not even ***exist*** when the Prospectus "became effective." *See Johnson v. Sequans Commc'ns S.A.*, 2013 WL 214297, at *12 (S.D.N.Y. Jan. 17, 2013) (dismissing Section 11 claim where offering

materials were not misleading given "facts as they existed" when materials became effective).[46] Regardless, the cough threshold issue does nothing to salvage Plaintiff's claims, which amount to a non-actionable, hindsight effort to "second guess how clinical trials are designed and managed." *Keryx*, 2014 WL 585658, at *1; *see supra* at 12, 22.

Plaintiff also claims that BELLUS improperly discussed gefapixant "without disclosing that the ***design*** of the Company's Phase 2 trial was materially different from Merck's and ***was resulting*** in a low number of severe cough patients being enrolled." (AC ¶ 218 (emphasis added); AC ¶¶ 8, 57 (same); AC ¶ 13 (similar)).) This allegation fails for a host of reasons. To start, Plaintiff's conclusory assertion does not even allege how RELIEF's "design" was "materially different" from Merck's. In any event, BELLUS ***did*** fully disclose its trial design (as did Merck), *see supra* at 5-7. Further, offering materials are judged "by assessing the facts as they existed" at the time of issuance. *Sequans Commc'ns*, 2013 WL 214297, at *12. Here, RELIEF enrollment began just two months before BELLUS issued the Prospectus, and did not finish for another six months. It was thus unknowable, based on the "facts as they existed" when the Prospectus was issued, whether RELIEF "was resulting" in high or low cough subjects. *See supra* at 5-7.

Plaintiff's Securities Act claims also fail because the Prospectus itself thoroughly and completely addresses every risk Plaintiff complains of. "Under the bespeaks caution doctrine, 'alleged misrepresentations in a stock offering are immaterial as a matter of law if it cannot be said that any reasonable investor could consider them important in light of adequate cautionary language set out in the same offering.'" *Rombach*, 355 F.3d at 173. Where, as here, a Prospectus "warns of the exact risk that later materialized, a [S]ection 11 claim will not lie as a matter of law."

[46] *In re HEXO Corp. Sec. Litig.*, 2021 WL 878589, at *9 (S.D.N.Y. Mar. 8, 2021) (dismissing Section 11 claim "based on hindsight pleading" where allegations turned on fact that "defendants had a contract with Quebec's government-run dispensary that turned out not to be as profitable as hoped for because demand was lower than expected").

In re ProShares Tr. Sec. Litig., 728 F.3d 96, 102 (2d Cir. 2013).[47] The Prospectus warned that BELLUS's trials could fail (Prospectus at S-12); that BELLUS may need to conduct another Phase 2 trial (*id.* at S-37); and that competitors could outcompete BELLUS (*id.* at S-15, S-48). When, ten months after the Prospectus, BELLUS announced RELIEF's results, the market was disappointed, but it could not have been ***surprised***. There was simply nothing more to disclose. *Aratana*, 315 F. Supp. 3d at 760 (dismissing Section 11 claims where "statements satisfactorily armed investors with all the information necessary to evaluate the risks" regarding timeline for commercially supplying company's drug).

B. The Securities Act Claims Are Time-Barred.

The Securities Act imposes a one-year limitations period on Section 11 and Section 12(a)(2) claims, 15 U.S.C. § 77m, which "commences 'when the plaintiff discovers (or should have discovered) the securities law violation.'" *Fed. Hous. Fin. Agency for Fed. Nat'l Mortg. Ass'n v. Nomura Holding Am., Inc.*, 873 F.3d 85, 119 (2d Cir. 2017). Here, the AC alleges Defendants "revealed the truth" of their alleged misstatements on July 6, 2020 by disclosing that "BLU-5937 had failed to meet its primary endpoint." (AC ¶¶ 1, 12.) Thus, the statute began to run on that date and expired on July 6, 2021. *Nomura*, 873 F.3d at 119. While Plaintiff first filed this case on March 16, 2021, it was not until the AC—filed on September 17, 2021—that Plaintiff added, for the first time, (a) Dr. Bonuccelli as a defendant and (b) claims under the Securities Act. These newly added claims—premised on an entirely new theory—are time barred, as neither addition "relates back" to the original complaint. *See* Fed. R. Civ. P. 15(c).

First, relation back can only apply to a new party where that party "knew or should have

[47] There "cannot be a material misstatement" if "defendants' statements explicitly disclosed the very risks about which plaintiff claims to have been misled." *Y-GAR Capital LLC v. Credit Suisse Gp, AG*, 2020 WL 71163, at *4 (S.D.N.Y. 2020); *Rubenstein v. Credit Suisse Gp. AG*, 457 F. Supp. 3d 289, 296 (S.D.N.Y. 2020) (same).

known that the action would have been brought against it, ***but for a mistake concerning the proper party's identity***." Fed. R. Civ. P. 15(c)(1)(C) (emphasis added). Plaintiff was not correcting any "mistake" by adding Dr. Bonuccelli: she was named in the Prospectus (at S-84) cited in the first complaint. Rather, the "original Complaint and [P]laintiff's conduct compel the conclusion that the failure to name [Bonuccelli] . . . was the result of a fully informed decision." *Hahn v. Office & Prof. Empl. Intern. Union*¸ 107 F. Supp. 3d 379, 384-85 (S.D.N.Y. 2015) (granting dismissal where plaintiff "simply neglected to sue another defendant who might also be liable").

Second, the AC's newly-added Securities Act claims do not "ar[i]se out of the conduct, transaction, or occurrence set out—or attempted to be set out—in the original pleading." Fed. R. Civ. P. 15(c)(1)(B). Claims relate back under Rule 15 only where they "render[] prior allegations more definite and precise." *Slayton v. Am. Express Co.*, 460 F.3d 215, 228 (2d Cir. 2006). Notably, an amended complaint that "complain[s] of statements made or omitted in the same Registration Statement and Prospectus" as the original complaint does not, standing alone, relate back. *In re Noah Educ. Holdings, Ltd. Sec. Litig.*, 2010 WL 1372709, at *9 (S.D.N.Y. Mar. 31, 2010). "Rather, relation back is ***only appropriate*** in securities actions where the new allegations relate to the same or similar conduct complained of in the original complaint." *Id*. (emphasis added; dismissing claim about "warning labels" where original complaint "focus[ed] solely on the omission of information about the cost of raw materials"); *In re Alcatel Sec. Litig.*, 382 F. Supp. 2d 513, 528 (S.D.N.Y. 2005) (dismissing claims concerning corporate acquisition disclosures, where original complaint "alleged buildup of obsolete inventory and [] downturn in demand").

Here, the AC's Securities Act claims do not "relate back" because they do not "relate to the same or similar conduct complained of in the original complaint." *In re Noah Educ.*, 2010 WL 1372709, at *9. The original complaint alleged that the Prospectus was misleading exclusively

because Defendants "failed to disclose" that "BLU-5937's 'high selectivity' . . . contributed to the drug potentially ***being less efficacious*** and thus likely not be able to meet the primary endpoint." (Compl. ¶ 42.) By contrast, rather than claiming Defendants omitted information about BLU-5937's ***efficacy***, the AC alleges that Defendants omitted information about the RELIEF trial's ***design***.[48] This "trial design" theory is entirely new, and was first put forth in an AC filed more than a year after the disclosure notifying Plaintiff of his purported claims. Accordingly, the Securities Act claims are time barred.

III. THE AC FAILS TO PLEAD STATUTORY STANDING.

Plaintiff fails to plead standing under both the Exchange Act and the Securities Act, as the AC alleges no facts about how Plaintiff allegedly acquired his BELLUS stock (or even where Plaintiff is located). (*See* AC ¶ 20.)[49] Accordingly, the AC's Exchange Act and the Securities Act claims should be dismissed for Plaintiff's failure to plead statutory standing:

Section 10(b), Exchange Act **–** Following the Supreme Court's guidance in *Morrison v. Nat'l Australia Bank Ltd.*, 561 U.S. 247 (2010), the Second Circuit has made clear that stock purchases of foreign companies "executed on a foreign exchange," even by a domestic buyer, does not fall within Section 10(b)'s ambit. *City of Pontiac Policemen's & Firemen's Ret. Sys.*, 752 F.3d at 181. Here, BELLUS is a Canadian company trading on a Canadian stock exchange. (Ex. 3 at S-26, S-28.) Because the AC does not plead that Plaintiff purchased his BELLUS stock domestically, as opposed to "a foreign exchange" (TSX), the AC fails to plead standing.

Section 12(a)(2), Securities Act **–** Plaintiff's 12(a)(2) claim is plainly deficient. "It is well-settled that a plaintiff may maintain a section 12(a)(2) claim only where the plaintiff purchased

[48] *See, e.g.*, AC ¶ 218 ("without disclosing that the design . . ."); AC ¶ 220 ("failed to disclose . . . its own poor design of its Phase 2 trial").

[49] While the original complaint contained a purported list of trades (which is not incorporated into the AC), even that did not allege how Plaintiff acquired his stock. (ECF. No. 1, Schedule A.)

securities directly in the initial public offering; so-called 'aftermarket' or 'secondary market' purchasers do not have standing." *In re Smart Techs., Inc. S'holder Litig.*, 295 F.R.D. 50, 57 (S.D.N.Y. 2013). The original complaint makes clear that Plaintiff is precisely such an "aftermarket or secondary market purchaser" who cannot bring this claim: he purchased his first shares in April 2020, not in BELLUS's September 2019 Offering. (ECF No. 1, Schedule A); *In re Fuwei Films Sec. Litig.*, 634 F. Supp. 2d 419, 445 (S.D.N.Y. 2009) (granting motion to dismiss section 12(a)(2) claims "on behalf of purchasers of Fuwei stock in the aftermarket," as liability "only attaches to plaintiffs who purchased their shares directly in the initial public offering").

Further, Section 12 "reaches only the buyer's immediate seller"; "a buyer cannot recover against his seller's seller." *Stadnick v. Vivint Solar, Inc.*, 2015 WL 8492757, at *16 (S.D.N.Y. Dec. 10, 2015), *aff'd,* 861 F.3d 31 (2d Cir. 2017); *Xiang v. Inovalon Holdings, Inc.*, 327 F.R.D. 510, 520 (S.D.N.Y. 2018) ("Section 12(a)(2) plaintiff must establish that it purchased the security ***directly from defendants*** through the public offering at issue" (emphasis added)). Here, the AC explicitly alleges that Plaintiff "did ***not buy in the IPO directly from BELLUS***." (AC Count IV at n.77 (emphasis added).) Plaintiff's claim should likewise be dismissed for this reason.

Section 11, Securities Act – To bring this claim, Plaintiff must be able to "***trace*** [his] shares to an allegedly misleading registration statement"—here, BELLUS's September 2019 U.S. Offering. *Inovalon*, 327 F.R.D. at 520 (emphasis added). The AC alleges only that Plaintiff "purchased BELLUS common stock traceable to the Company's false and/or misleading IPO Documents," (AC ¶ 20), but that "threadbare recital[] of the elements . . . supported by mere conclusory statements, do[es] not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Notably, here, prior to its September 2019 Offering, BELLUS "had a limited trading market for [its] common shares in the United States on the over-the-counter market," and BELLUS

had "44,199,209 common shares outstanding" and openly trading on TSX. (Ex. 3 at S-6, S-28, S-76.) BELLUS cross-listed the shares distributed in the Offering on TSX, confirming on September 9, 2019 that its shares were "now dual-listed on [NASDAQ] and [TSX]." (Ex. 33, 9/9/19 Press Release.)[50] Yet the AC alleges no facts showing that Plaintiff's shares are "traceable to" BELLUS's September 2019 IPO, as opposed to BELLUS's (i) preexisting shares already trading on the U.S. over-the-counter market; or (ii) 44-million-plus preexisting shares already trading on TSX prior to the Offering, and then dual-listed on NASDAQ after the Offering. Plaintiff thus fails to plead statutory standing. *See Smart Techs*, 295 F.R.D. at 56 (where "putative class members purchased . . . securities, in Canada—or anywhere else outside the United States—they do not have a viable cause of action," as Securities Act claims require that a plaintiff "purchased a security listed on a domestic exchange or engaged in a 'domestic transaction in other securities.'").

Moreover, Plaintiff did not buy his shares until April 2020 (*see* ECF No. 1, Schedule A), more than four months after the expiration of the 90-day post-Offering "lock-up" period in which "BELLUS, our officers and directors, and certain affiliated with our directors," agreed not to sell their BELLUS stock.[51] Again, the AC pleads no facts showing that Plaintiff's shares are traceable to the Offering, as opposed to unregistered, pre-Offering shares previously owned by BELLUS insiders, which became tradeable 90 days post-Offering (*i.e.*, in December 2019). *See In re Initial Public Offering Sec. Litig.*, 227 F.R.D. 65 (S.D.N.Y. 2004), *rev'd on other grounds*, 471 F.3d 24 (2d. Cir. 2006) (it is "virtually impossible to trace shares to a registration statement once additional unregistered shares have entered the market"); *In re Crazy Eddie Sec. Litig.*, 792 F. Supp. 197, 202

[50] *See, e.g.*, Oxford Reference, *A Dictionary of Finance and Banking* 110 (Jonathan Law & John Smullen, eds., 4th ed. 2008) (defining "cross-border listing" as "[t]he practice of listing shares in a company on the stock exchanges of different countries in order to create a larger market for the shares").

[51] Ex. 3 at S-76 ("This restriction terminates after the close of trading of the common shares on and including the 90th day after the date of this [September 5, 2019] prospectus supplement")); *id.* Ex. D.

(E.D.N.Y. 1992) (shares must be "traceable to the allegedly defective offerings and not . . . registration-exempt sales made by . . . former management [members] pursuant to Rule 144.").

IV. PLAINTIFF'S CONTROL PERSON CLAIMS FAIL.

The control person liability claims under Section 20 of the Exchange Act and Section 15 of the Securities Act fail because these claims are "necessarily predicated on a primary violation of securities law," and the AC fails to allege any such violation. *Rombach*, 355 F.3d at 177-78.

V. THE AC FAILS TO ALLEGE PERSONAL JURISDICTION.

Finally, the AC should be dismissed for failure to allege personal jurisdiction over the BELLUS Defendants. ***First***, the AC fails to allege general personal jurisdiction, because neither Canada-based BELLUS or its employees (including the Individual Defendants) are alleged to be "at home" in the United States. (AC ¶¶ 21-26.) *See Daimler AG v. Bauman*, 571 U.S. 117, 138-39 (2014). ***Second***, the AC fails to allege facts supporting specific personal jurisdiction because Plaintiff fails to allege a "cause of action arising from the [] effects" of the BELLUS Defendants' alleged conduct in the United States. *In re Parmalat Sec. Litig.*, 376 F. Supp. 2d 449, 456-57 (S.D.N.Y. 2005). Specifically, the AC alleges no facts showing that Plaintiff's alleged BELLUS stock purchases have a nexus to the United States. Indeed, Plaintiff does not even allege that he purchased BELLUS's stock—or what amounts he purchased and when—on ***NASDAQ*** at all (as opposed to TSX, for instance, where BELLUS's stock was also publicly trading in Canada throughout the Class Period). (*See* AC ¶ 20.) Because Plaintiff has not "claim[ed] to have purchased [BELLUS] securities in the United States," the AC should be dismissed for lack of personal jurisdiction. *In re Parmalat Sec. Litig.*, 376 F. Supp. 2d at 456-57 (dismissing plaintiffs for lack of personal jurisdiction where they did not allege stock purchases in the United States).

CONCLUSION

For all of these reasons, the Court should dismiss the AC with prejudice.

Dated: November 16, 2021

Respectfully submitted,

BELLUS HEALTH, INC., ROBERTO BELLINI, FRANÇOIS DESJARDINS, AND DR. CATHERINE BONUCCELLI

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CERTIFICATE OF SERVICE

I hereby certify that on November 16, 2021, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which sent notification of such filing to all attorneys of record.

/s/ Caroline H. Bullerjahn
Caroline H. Bullerjahn